



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 878

[Docket No. FDA-2016-N-0400]

General and Plastic Surgery Devices; Reclassification of Blood Lancets

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed order.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is proposing to reclassify the following three types of blood lancets used to puncture skin to obtain a drop of blood for diagnostic purposes from class I (general controls) exempt from premarket notification into class II (special controls) and subject to premarket review: Single use only blood lancets with an integral sharps injury prevention feature, single use only blood lancets without an integral sharps injury prevention feature, and multiple use blood lancets for single patient use only. FDA is identifying proposed special controls for these types of blood lancets that we believe are necessary to provide a reasonable assurance of safety and effectiveness. FDA is also proposing to reclassify multiple use blood lancets for multiple patient use from class I (general controls) exempt from premarket notification into class III (premarket approval). FDA is proposing the reclassification of these four types of blood lancets on its own initiative based on new information.

DATES: Submit either electronic or written comments on the proposed order by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 (PRA)

by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER], (see the "Paperwork Reduction Act of 1995" section of this document). See section X of the SUPPLEMENTARY INFORMATION section of this document for the proposed effective date of any final order that may publish based on this proposal.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2016-N-0400 for "General and Plastic Surgery Devices; Reclassification of Blood Lancets." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing

and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at:

<http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Submit comments on information collection issues to the Office of Management and Budget (OMB) in the following ways:

- Fax to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or email to oir_submission@omb.eop.gov. All comments should be identified with the title, "General and Plastic Surgery Devices; Reclassification of Blood Lancets."

FOR FURTHER INFORMATION CONTACT: Joshua Nipper, Center for Devices and

Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. G422, Silver Spring, MD 20993-0002, 301-796-6524; or Stephen Ripley, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended, established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the FD&C Act (21 U.S.C. 360c) established three categories (classes) of devices, reflecting the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Section 513(a)(1) of the FD&C Act defines the three classes of devices. Class I devices are those devices for which the general controls of the FD&C Act (controls authorized by or under section 501, 502, 510, 516, 518, 519, or 520 (21 U.S.C. 351, 352, 360, 360f, 360h, 360i, or 360j) or any combination of such sections) are sufficient to provide reasonable assurance of safety and effectiveness; or those devices for which insufficient information exists to determine that general controls are sufficient to provide reasonable assurance of safety and effectiveness or to establish special controls to provide such assurance, but because the devices are not purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, and do not present a potential unreasonable risk of illness or injury, are to be regulated by general controls (section

513(a)(1)(A) of the FD&C Act). Class II devices are those devices for which general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but for which there is sufficient information to establish special controls to provide such assurance, including the promulgation of performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines, recommendations, and other appropriate actions the Agency deems necessary to provide such assurance (section 513(a)(1)(B) of the FD&C Act). Class III devices are those devices for which insufficient information exists to determine that general controls and special controls would provide a reasonable assurance of safety and effectiveness, and are purported or represented for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or present a potential unreasonable risk of illness or injury (section 513(a)(1)(C) of the FD&C Act). Under section 513(d)(1) of the FD&C Act, devices that were in commercial distribution before the enactment of the 1976 amendments, May 28, 1976 (generally referred to as "preamendments devices"), are classified after FDA: (1) Receives a recommendation from a device classification panel (an FDA advisory committee); (2) publishes the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) publishes a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

Devices that were not in commercial distribution before May 28, 1976 (generally referred to as "postamendments devices") are classified automatically by section 513(f) of the FD&C Act into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval, unless and until: FDA reclassifies the device into class I or II; or FDA issues an order finding the device to be substantially equivalent, in accordance with section

513(i) of the FD&C Act, to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to previously marketed devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 of the regulations (21 CFR part 807). A person may market a preamendments device that has been classified into class III through premarket notification procedures without submission of a PMA until FDA issues a final order under section 515(b) of the FD&C Act (21 U.S.C. 360e(b)) requiring premarket approval.

On July 9, 2012, Congress enacted the Food and Drug Administration Safety and Innovation Act (FDASIA). Section 608(a) of FDASIA amended section 513(e) of the FD&C Act, changing the reclassification process from rulemaking to administrative order. Section 513(e)(1) of the FD&C Act sets forth the process for issuing a final order. Specifically, prior to the issuance of a final order reclassifying a device, the following must occur: Publication of a proposed order in the Federal Register, a meeting of a device classification panel described in section 513(b) of the FD&C Act, and consideration of comments to a public docket. The proposed reclassification order must set forth the proposed reclassification and a substantive summary of the valid scientific evidence concerning the proposed reclassification, including the public health benefits of the use of the device, and the nature and incidence (if known) of the risk of the device. (See section 513(e)(1)(A)(i) of the FD&C Act.)

Section 513(e)(1) provides that FDA may, by administrative order, reclassify a device based on "new information." FDA can initiate a reclassification under section 513(e) or an interested person may petition FDA. The term "new information," as used in section 513(e) of the FD&C Act, includes information developed as a result of a reevaluation of the data before

the Agency when the device was originally classified, as well as information not presented, not available, or not developed at that time. (See, e.g., Holland-Rantos v. United States Dep't of Health, Educ. & Welfare, 587 F.2d 1173, 1174 n.1 (D.C. Cir. 1978); Upjohn v. Finch, 422 F.2d 944 (6th Cir. 1970); Bell v. Goddard, 366 F.2d 177 (7th Cir. 1966).)

Reevaluation of the data previously before the Agency is an appropriate basis for subsequent regulatory action where the reevaluation is made in light of newly available regulatory authority (see Bell v. Goddard, 366 F.2d at 181; Ethicon, Inc. v. FDA, 762 F.Supp. 382, 389-91 (D.D.C. 1991)), or in light of changes in "medical science." (See Upjohn v. Finch, 422 F.2d at 951.) Whether data before the Agency are past or new data, the "new information" to support reclassification under section 513(e) must be "valid scientific evidence," as defined in section 513(a)(3) of the FD&C Act and 21 CFR 860.7(c)(2). (See, e.g., General Medical Co. v. FDA, 770 F.2d 214 (D.C. Cir. 1985); Contact Lens Mfrs. Assoc. v. FDA, 766 F.2d 592 (D.C. Cir. 1985), cert. denied, 474 U.S. 1062 (1985).)

II. Regulatory History of the Device

Blood lancets were classified in part 878 (21 CFR part 878) in a final rule published in the Federal Register on June 24, 1988 (53 FR 23856) that classified 51 general and plastic surgery devices. This 1988 rule classified blood lancets into class I (general controls). These devices were grouped with other devices under "Manual surgical instrument for general use" in § 878.4800 (21 CFR 878.4800). At the time, blood lancets had been in common use in medical practice for many years, and FDA believed that general controls were sufficient to provide reasonable assurance of the safety and effectiveness of those devices. The rule was amended on April 5, 1989 (54 FR 13826) to clarify that manual surgical instruments for general use made of

the same materials as used in preamendment devices were exempt from premarket notification 510(k) review.

On December 7, 1994, FDA further amended the classification when it published a final rule in the Federal Register (59 FR 63005) that exempted 148 class I devices from premarket notification, with limitations. Blood lancets were one of those devices. FDA determined that manufacturers' submissions of premarket notifications were unnecessary for the protection of the public health and that FDA's review of such submissions would not advance its public health mission.

On August 26, 2010, FDA and the Centers for Disease Control and Prevention (CDC) issued a joint initial communication warning that the use of fingerstick devices (blood lancets) to obtain blood from more than one patient posed a risk of transmitting bloodborne pathogens. The communication was updated on November 29, 2010 (Ref. 1). FDA's communication update, "Use of Fingerstick Devices on More Than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication: Update 11/29/2010" stated that "[o]ver the past 10-15 years, the CDC and FDA have noted a progressive increase in reports of bloodborne infection transmission (primarily hepatitis B virus [HBV]) resulting from the shared use of fingerstick and POC [or 'Point of Care'] blood testing devices." FDA and CDC recommended, among other things, that health care professionals and patients never use a blood lancet for more than one person.

On November 29, 2010, FDA published a guidance entitled "Guidance for Industry and Food and Drug Administration Staff; Blood Lancet Labeling" (75 FR 73107) (Ref. 2). This guidance includes labeling recommendations to address concerns that both health care providers

and patients may be unaware of the serious adverse health risks associated with using the same blood lancet for assisted withdrawal of blood from more than one patient, even when the blood lancet blade is changed for each blood draw. FDA recommends in the guidance that all blood lancets be labeled for use only on a single patient. FDA recommends in the guidance that a statement limiting use to a single patient should also appear on the label attached to the device, if possible. The guidance was for immediate implementation. When final, this order will supersede this labeling guidance.

On June 26, 2013, FDA held a meeting of the General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee (the Panel) to discuss the potential reclassification of blood lancets (Ref. 3). The Panel discussed new scientific information (see section VII of this document), the risks to health from blood lancets, whether blood lancets should be reclassified or remain in class I, and possible special controls for these devices if reclassified into class II. The Panel agreed that general controls were not sufficient to provide a reasonable assurance of safety and effectiveness of any of the four types of blood lancets (the four types are explained in section III). The Panel believed that because multiple use blood lancets for multiple patient use presented a potential unreasonable risk of illness or injury, and insufficient information existed to establish special controls for these devices, they should be reclassified into class III. The Panel recommended that all other blood lancet devices be reclassified into class II (special controls). FDA is not aware of new information since this Panel meeting that would provide a basis for a different recommendation or findings.

III. Device Description

A blood lancet is used to puncture the skin to obtain small blood specimens for testing

blood glucose, hemoglobin, and other blood components. Some blood lancets are used with POC blood testing devices, such as blood glucose meters and Prothrombin Time and International Normalized Ratio (PT/INR) anticoagulation meters. Today, probably the most common use for a blood lancet is in diabetes monitoring. These devices are used in both home and professional health care settings. Only a small blood sample is needed for testing of blood glucose level. The blood sample is dropped onto a test strip and inserted into a blood glucose meter for results.

FDA has identified four subsets of blood lancets:

1. A single use only blood lancet with an integral sharps injury prevention feature is a disposable blood lancet intended for a single use that is comprised of a single use blade attached to a solid, non-reusable base (including an integral sharps injury prevention feature) that is used to puncture the skin to obtain a drop of blood for diagnostic purposes. The integral sharps injury prevention feature allows the device to be used once and then renders it inoperable and incapable of further use;
2. A single use only blood lancet without an integral sharps injury prevention feature is a disposable blood lancet intended for a single use that is comprised of a single use blade attached to a solid, non-reusable base that is used to puncture the skin to obtain a drop of blood for diagnostic purposes;
3. A multiple use blood lancet for single patient use only is a multiple use capable blood lancet intended for use on a single patient that is comprised of a single use blade attached to a solid, reusable base that is used to puncture the skin to obtain a drop of blood for diagnostic purposes; and

4. A multiple use blood lancet for multiple patient use is a multiple use capable blood lancet intended for use on multiple patients that is comprised of a single use blade attached to a solid, reusable base that is used to puncture the skin to obtain a drop of blood for diagnostic purposes.

IV. Proposed Reclassification

A. Single Patient Use Only Blood Lancets

FDA is proposing to reclassify the following three subsets of blood lancets from class I (general controls) exempt from premarket review to class II (special controls) and subject to premarket review: (1) Single use only blood lancets with an integral sharps injury prevention feature, (2) single use only blood lancets without an integral sharps injury prevention feature, and (3) multiple use blood lancets for single patient use only. FDA believes that general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness for these devices, and that there is sufficient information to establish special controls to provide such assurance.

The Food and Drug Administration Modernization Act (FDAMA) (Pub. L. 105-115) added section 510(m) to the FD&C Act. Section 510(m) of the FD&C Act provides that a class II device may be exempted from the premarket notification requirements under section 510(k) of the FD&C Act, if the Agency determines that premarket notification is not necessary to assure the safety and effectiveness of the device. The Agency does not intend to exempt these devices from premarket notification (510(k)) submission as allowed under section 510(m) of the FD&C Act. FDA believes premarket notification is necessary for these devices to provide a reasonable assurance of safety and effectiveness.

B. Multiple Patient Use Blood Lancets

FDA is proposing that a fourth subset of blood lancets, multiple use blood lancets for multiple patient use, be reclassified from class I (general controls) without premarket review to class III (premarket approval). FDA believes that insufficient information exists to determine that general controls and special controls would provide a reasonable assurance of safety and effectiveness for these devices, which present a potential unreasonable risk of illness or injury (see section 513(a)(1)(C) of the FD&C Act).

Elsewhere in this issue of the Federal Register, FDA is proposing to require the filing of a PMA or notice of completion of a product development protocol (PDP) for these devices, which will be finalized only if FDA reclassifies multiple use blood lancets for multiple patient use to class III.

FDA continues to believe that multiple use blood lancets for use in multiple patients present significant risks to public health. Specifically, multiple patient use blood lancets pose a risk of transmission of bloodborne pathogen infections, including HBV and hepatitis C. Bloodborne pathogens may be transmitted between patients by blood or blood products taken from a patient with a transmissible infection. FDA believes that certain design characteristics would be required to help mitigate these risks. For example, multiple use blood lancets for use in multiple patients would need to be designed to allow for rigorous, thorough cleaning plus a disinfection or sterilization process capable of reduction of bloodborne pathogens to a clinically acceptable level between each use in a different patient in order to be safe for this intended use. The cleaning and disinfection/sterilization process to be used to render a multiple use blood lancet safe for use in multiple patients would need to be effective in spite of potential health care

provider noncompliance with manufacturer's Instructions for Use. More importantly, the multiple use blood lancet for use in multiple patients would need to be designed such that repeat operation of the device is not possible until the device has been thoroughly cleaned and disinfected, using validated processes, by the health care user. Such a mechanism is necessary to prevent health care providers, especially those working in facilities that provide relatively little staff education or supervision, such as assisted living facilities (ALF), from failing to comply with manufacturer recommendations regarding rendering multiple patient use blood lancets safe for use in more than one patient. Therefore, the safety of the multiple use blood lancets for multiple patients, especially the effectiveness of their design and reprocessing instructions to render the device safe for use on more than one patient and the ability of health care providers to follow these instructions completely, must be rigorously demonstrated, independently of any other blood lancet. Because blood lancets for use on multiple patients present a potential unreasonable risk of illness or injury and insufficient information exists for FDA to determine that special controls would provide reasonable assurance of safety and effectiveness of the device, the Agency believes that these devices should be reclassified into class III.

V. Public Health Benefits and Risks to Health

As required by section 513(e)(1)(A)(I) of the FD&C Act, FDA is providing a substantive summary of the valid scientific evidence regarding the public health benefit of blood lancets, and the nature and, if known, the incidence of the risk of the devices. Since the 1990s, because of outbreaks of HBV infections associated with blood lancets and meters used in blood glucose monitoring, CDC and FDA have recommended that blood lancets should be limited to one individual's use (Refs. 1 and 4 to 6). Nevertheless, there have been continuing reports of

bloodborne pathogen transmission from the shared use of blood lancets. Improper use of blood lancets can endanger public health, and FDA is concerned about the persistent risk of transmission of hepatitis and other bloodborne pathogens when blood lancets are used to obtain blood from more than one patient in health care settings. Certain bloodborne pathogens, such as HBV, are very stable at ambient temperatures and HBV infected patients, who often lack clinical symptoms of hepatitis, can have high concentrations of HBV in their blood or body fluids, thus serving as unsuspected sources of the infectious agent available for transmission to other patients when blood lancets are misused (Refs. 7 to 32).

These findings were discussed by the June 26, 2013, General and Plastic Surgery Devices Panel. The Panel agreed that the risks to health identified in this section are applicable to blood lancet devices, particularly the risk of cross-contamination between patients when the same lancet is used on multiple patients (Ref. 3).

After considering the information discussed by the Panel and in published literature, as well as medical device reports relating to blood lancets, and reported outbreaks of various bloodborne pathogen infections, FDA believes that the risks to health associated with the use of blood lancets are (1) bloodborne pathogen transmission, (2) sharp object injuries, (3) local tissue infections, and (4) adverse tissue reaction (not infection). The June 26, 2013, Panel also believed that these were the risks for the device (Ref. 3).

A. Bloodborne Pathogen Transmission

Bloodborne pathogens such as HBV, hepatitis C virus, and potentially any other pathogen present in the bloodstream of a patient can be transmitted from one patient to another by the following mechanisms:

- Reuse of the same lancet blade to draw blood from more than one patient or
- Failure/inability to adequately clean the base of a multiple use blood lancet resulting in the blood contamination of the next "new" lancet blade when blood is drawn from more than one patient.

B. Sharp Object Injuries

The blade of a blood lancet device is designed to pierce the skin and draw blood. Except when the used lancet blade is immediately and automatically covered by a sharps safety feature, which renders the blade inaccessible, the exposed sharp blade of a blood lancet presents a puncture hazard to anyone coming in contact with it. Blade exposure can result due to either the lack of a sharps safety feature or device breakage.

C. Local Tissue Infections

Human skin always carries a population of bacteria and often fungi (normal skin flora), which causes no problem for the host when skin is intact. However, puncture injuries to the skin by sharp objects such as blood lancet blades can carry these microbes into the normally sterile tissue below the skin. Such injuries have the potential to cause local skin/soft tissue infections.

D. Adverse Tissue Reaction (Not Infection)

Tissue contact with some materials, metals, and material colorants can cause skin inflammation, irritation, or exanthems (rashes). These reactions may be due to either hypersensitivity to a specific compound/metal or to a non-specific reaction.

VI. Summary of Reasons for Reclassification

FDA believes that blood lancets for use on a single patient only should be reclassified into class II because special controls, in addition to general controls, can be established to

provide reasonable assurance of safety and effectiveness of the device. FDA further believes that blood lancets for use on multiple patients should be reclassified into class III because multiple patient use blood lancets present a potential unreasonable risk of illness or injury and insufficient information exists for FDA to determine that special controls would provide reasonable assurance of safety and effectiveness of the device.

The June 26, 2013 reclassification Panel recommended that single patient blood lancets be reclassified into class II and multiple patient blood lancets into class III. The Panel did not believe that general controls alone were sufficient to ensure the safety and effectiveness of blood lancets. The Panel believed that special controls could be established to provide reasonable assurance of the safety and effectiveness of single use blood lancets, with and without integral sharps injury prevention features, and multiple use lancets for single patients, but that special controls could not be established to provide reasonable assurance of safety and effectiveness for multiple use lancets for multiple patients. Hence, the Panel agreed that blood lancets for use on a single patient only should be reclassified into class II (special controls), and multiple use lancets for multiple patients should be reclassified into class III (premarket approval).

VII. Summary of Data Upon Which the Reclassification Is Based

FDA uses the bloodborne pathogens definition in 29 CFR 1910.1030(b). Bloodborne pathogens, such as HBV, may be transmitted between patients by blood and certain body fluids (Ref. 32). Since HBV-infected patients, who often lack clinical symptoms of hepatitis, have high concentrations of HBV in their blood and HBV is stable at ambient temperatures, transmission of HBV may result from exposure to equipment that has not been adequately disinfected or by the misuse of "single use only" medical devices (e.g., needles and syringes) (Ref. 33).

The history of recognized bloodborne pathogen transmission by blood lancets may have started in 1923 when an outbreak of jaundice occurred in the Goteborg Hospital diabetic clinic in Sweden, which was described by Schmid, et al. (Ref. 10). All patients had blood drawn for glucose testing from their ear lobes by a spring-activated "Schnepper" device, which was cleaned "perfunctorily" between uses. As a result, 26 clinic patients developed jaundice. Outbreaks of hepatitis in English diabetic patients were described by Graham in 1938 (Ref. 11) and by Droller in 1945 (Ref. 12). In both of these outbreaks, venous blood for glucose measurement was drawn using syringes that were only chemically disinfected between uses while the needles were boiled; cleaning procedures were not mentioned in the reports. Syringes and needles are now single-use-only devices because the procedures used to reprocess these devices many years ago have long been recognized to be inadequate, resulting in outbreaks of hepatitis transmission (Ref. 10). There were also two case reports, in 1985 and 1997, of the transmission of HBV infection due to sharing personal use blood lancets for home glucose monitoring with one other person who already had HBV. One report was from the United States and one was from Hungary (Refs. 13 and 14). In addition, Mendez et al. reported a 75-year-old patient with diabetes who died of acute hepatitis, whose only risk factor for HBV infection appeared to be her diabetic care at a local outpatient facility where she had repeated fingersticks for blood glucose monitoring (Ref. 15).

During the 1990s, several bloodborne pathogen transmission issues led to CDC and FDA involvement. In 1990, CDC learned of a nosocomial outbreak of HBV transmission due to the use of a spring-loaded lancet device whose disposable platform was not removed and discarded

after each use of the device while it was used for the care of multiple patients (Ref. 4).¹ CDC reported this outbreak to FDA; FDA then issued a safety alert warning users of the precautions needed for the safe use of this device (Ref. 5). This was the first reported outbreak of HBV transmission associated with the use of a blood lancet device in the United States (Refs. 5 and 7).

CDC's outbreak investigation revealed that a patient who had diabetes and also a chronic HBV infection caused by a relatively rare viral subtype was admitted to the outbreak ward in 1989. Twelve of the 23 patients who acquired HBV after admission to the same ward as the chronic HBV source patient were serotyped, and all were found to have the same viral subtype causing their HBV infections. The first nosocomially infected patient had a very long-term stay on the ward and so served as a source of transmission to other patients over a period of 12 months. Twenty of the 23 outbreak patients had diabetes; they and the three other case-patients all experienced numerous POC fingerstick blood draws with the same type of blood lancet while hospitalized on the outbreak ward. The implicated blood lancet device included a disposable platform to stabilize the patient's finger; the single use lancet blade penetrated a hole in that platform to reach the patient's skin. Half the ward nursing staff who performed fingersticks with this lancet acknowledged not changing the device platform with each use of the lancet. A similar outbreak of hepatitis transmission was reported in 1990 in France in which a similar blood lancet device was implicated. Douvin et al. (Ref. 8) reported that examination of the device implicated in the French outbreak showed visible blood contamination of the lancet platform in 24 percent of studied uses of that device. Shier et al. (Ref. 9) reported in 1993 that the use of another

¹ Hepatitis B and hepatitis C infections, as well as other bloodborne infections such as HIV infection, are reported to State health departments and, by them, to CDC; FDA does not usually receive such reports directly from health care facilities or personnel, even when a medical device has transmitted the infection.

spring-loaded lancet device in a volunteer study of blood glucose levels resulted in visible blood contamination on 29 percent of the device end caps. This device was intended for "personal" use only.

As a result of the 1990 outbreak of HBV transmission due to blood lancet use in the United States, FDA and CDC recommended that spring-loaded blood lancet devices should have only single use only "platforms" as well as single use only blades; the devices were to be cleaned and disinfected per the manufacturer's instructions (Refs. 4 and 5). The 1990 FDA Safety Alert also advised "Devices [blood lancets] without a removable platform should only be used with one patient in the hospital or outpatient setting. After the patient is discharged, the device may be reused only if it is disinfected according to the manufacturer's instructions. If there are no instructions for disinfection, the device should be discarded."

Since 1990, the incidence of diabetes mellitus has increased significantly in the United States, especially in adults aged 65-79 (Refs. 34 and 35). At the same time, clinical practice in the care of these patients increasingly emphasized the need for improved blood glucose level control, resulting in the increased use of POC blood glucose monitoring both in health care facilities and at home (Refs. 36 to 38). Unfortunately, along with the increased incidence of diabetes has come a progressive increase in the reports of bloodborne infection transmission (primarily HBV), resulting from the shared use of fingerstick and POC blood testing devices (Ref. 1). In 2011, the CDC reported that 25 of 29 outbreaks of HBV infection occurring in long-term care facilities since 1996 involved adults with diabetes receiving assisted blood glucose monitoring (Ref. 39).

In 1997, CDC reported two outbreaks of HBV transmission, one in a nursing home in

Ohio and one in a hospital in New York City (NYC) (Ref. 16). Two different blood lancet devices were used at the two sites. However, both lancet devices included the use of an "end cap" that came in contact with patient skin. This was a separate, individual use component of the lancet device used in Ohio; the nursing home was reusing both the lancet and the cap for multiple patients. The end cap was a part of the disposable, single use only lancet blade assembly in the device used in NYC. The exact mechanism of blood transmission was not entirely clear in the NYC setting; staff claimed they had discarded the end cap after each use. CDC postulated that either blood-contaminated nurses gloves worn for the care of multiple patients or the pen-like lancet-holding device itself might have been the source of the blood cross-contamination of the lancet. A similar outbreak was reported by Quale et al. in 1998 from a hospital in New York (Ref. 17). The recognition of 3 cases of nosocomially acquired HBV infection resulted in an investigation that uncovered another 11 cases. Reuse by hospital staff of a disposable lancet end cap with the lancet in multiple patients was identified as the probable cause of hepatitis cross-transmission to patients; contamination of the lancet wound from blood on unchanged gloves worn by nurses during collection of blood samples from multiple patients may also have contributed to the nosocomial transmission of HBV in this outbreak.

CDC reviewed the incidence of reported outbreaks of HBV and hepatitis C infection in nonhospital health care settings between 1998 and 2008 and noted a significant increase in such nosocomial transmission of bloodborne pathogens (Refs. 18 to 21). N.D. Thompson et al. identified 33 outbreaks of nosocomial hepatitis transmission in nonhospital health care settings (Ref. 18). Of these 33 outbreaks, 15 were found to be due to blood glucose monitoring in long-term care facilities. Only half of these outbreak investigations were published in the scientific

literature; the others were recognized by health department investigations and reports to CDC. In 9 of the 15 outbreaks of nosocomial hepatitis in patients with diabetes, blood lancet devices were shared among multiple patients. In two additional outbreaks, lancets were not noted to be shared, but blood-soiled glucose meters were stored together with lancets without cleaning/disinfection of the devices and gloves were not regularly changed between each patient. These failures of proper infection control practice could have led to blood contamination of individual blood lancets in these two facilities.

N.D. Thompson et al. also investigated blood glucose monitoring practices in long-term care facilities in Pinellas County, FL, in 2007 and found that 22 percent of the participating facilities that used reusable fingerstick devices used them in multiple patients (Ref. 22). Patel et al. reported in 2009 on the efforts of the Virginia Department of Health to improve blood glucose monitoring practices in ALFs in Virginia (Ref. 23). This effort followed two separate outbreaks of HBV infections in two ALFs. In those outbreaks, one of the three acutely symptomatic initial patients died of HBV infection. Of 68 patients undergoing blood glucose monitoring in these 2 facilities, a total of 11 patients acquired HBV infection. Both facilities used reusable blood lancets to obtain blood from multiple patients and did not clean or disinfect them between uses. The Virginia Department of Health then mailed an educational packet on safe blood glucose monitoring practices to all ALFs (640) in the State. A random sample of ALFs was contacted after the educational intervention and invited to participate in a survey to evaluate the response to the educational packet. The results found that 16 percent of the facilities that used lancets to monitor blood glucose levels were still using these devices to obtain blood from multiple patients.

Y.G. McIntosh et al. investigated outbreaks of nosocomial HBV transmission in four ALFs between 2009 and 2011 and found that in all four facilities, pen-style lancets were used to obtain blood for glucose monitoring from multiple patients even though two facilities provided each patient with dedicated "single patient use only pen-style lancets" according to their policies (Ref. 24). Z. Moore et al. reported another outbreak of nosocomial HBV transmission in an ALF in North Carolina in 2010 in which blood lancet devices were shared among multiple patients. Six of the eight elderly patients who acquired acute HBV in this outbreak died from complications of hepatitis (Ref. 25). M.K. Schaefer et al. surveyed a stratified, random sample of ambulatory surgery centers (ASCs) in three volunteer states in 2009 (Ref. 26). Of the 53 ASCs that performed blood glucose monitoring, 11 (21 percent) reused pen-style blood lancets on multiple patients and 17 (32 percent) also failed to clean and disinfect blood glucose meters after each use.

Thompson and Schaefer reported the analysis of four outbreaks of nosocomial HBV in ALFs in 2009-2010 (Ref. 27). One was also reported separately by Z. Moore et al. (Ref. 24). Two of the three other outbreaks occurred in Virginia and one in Florida; these 3 outbreaks resulted in 21 new patients acquiring acute HBV. In two of the three facilities, use of reusable blood lancets to draw blood from multiple patients was observed or reported. The third facility denied that it permitted the sharing of reusable lancets. However, used lancets and glucose meters were stored together, along with clean supplies; visible blood contamination was observed on several glucose meters and one reusable lancet by the investigator. Thompson and Schaefer also reported in their paper on two patient notification campaigns resulting from the misuse of reusable blood lancets with preloaded lancet cartridges, intended and cleared only for

single patient use, which were used to obtain blood from multiple patients. One episode involved a community health center and was reported when personnel noted that the lancet blades were not retracting properly, which might have resulted in blade use for more than one patient. The second episode occurred at a community health fair in which physician assistant students were offering diabetes screening. During the fair, the students realized that the lancet blades had not been advanced properly so that each patient received a new blade. The first episode exposed 283 patients to a contaminated lancet blade; the second incident exposed approximately 60 patients. The results of the patient notification studies were not reported.

As a result of this significant increase in such nosocomial transmission of bloodborne pathogens, on August 26, 2010, FDA and the CDC issued a Safety Communication (Ref. 1) and a Clinical Reminder (Ref. 6), respectively, warning that the use of blood lancets to obtain blood from more than one patient risks the transmission of bloodborne pathogen infections from one patient to other patients. Both FDA and CDC recommended that blood lancets should never be used to obtain blood from more than one patient. In addition, the Centers for Medicare and Medicaid Services issued a Survey and Certification Memorandum for Point of Care Devices and Infection Control in Nursing Homes identifying the use of blood lancet devices for more than one patient as an infection control standards deficiency (Ref. 40). On November 29, 2010, FDA issued "Guidance for Industry and Food and Drug Administration Staff: Blood Lancet Labeling," which provided guidance for lancet manufacturers on the labeling of all blood lancets, including those capable of reuse, as "single patient use only" devices (Ref. 2).

In 2012, another outbreak of acute HBV was reported in an ALF in Virginia (Ref. 28). The source patient had been recently transferred from another ALF where she had acquired

nosocomial HBV infection from the shared use of blood lancets for multiple patients (Ref. 24). This ALF also reused blood lancets to obtain blood from multiple patients for glucose monitoring. This dangerous practice resulted in two new nosocomial HBV infections in this ALF.

Outbreaks of hepatitis transmission due to use of blood lancets to draw blood from more than one patient for blood glucose monitoring have not been limited to the United States. In 2001, Desenclos et al. described an outbreak of nosocomial hepatitis C transmission in an inpatient ward for children with cystic fibrosis and diabetes in a French hospital in 1994-1995 (Ref. 29). Blood glucose monitoring was done by the nursing staff for the patients with cystic fibrosis as well as for the patients with diabetes using a spring-loaded lancet with a disposable platform to stabilize the finger. These devices were shared among patients between 1986 and 1992 during repeated admissions to the inpatient unit. After 1992, patients were supposed to use only their own lancet devices for blood glucose monitoring. The retrospective prevalence of prior hepatitis C infection was found to be 58 percent in patients with cystic fibrosis and 17 percent in patients with diabetes in 1994. At the time (1994), the prevalence of antibody to hepatitis C in the general public in France was 1.1 percent. The patients with cystic fibrosis had more frequent and longer admissions to the inpatient ward and more of the exposed cystic fibrosis patients (66.7 percent) were screened for hepatitis C infection than were the patients with diabetes admitted to the inpatient ward during the exposure period (39.5 percent). These factors may have influenced the apparent difference in hepatitis C transmission in these two groups of exposed patients.

In 2005, De Schrijver et al. described an outbreak of acute HBV infection in a nursing

home in Antwerp (Ref. 30). The initial report of a fulminant case of acute HBV infection in an 83-year-old resident of the home resulted in an investigation that identified acute HBV infection in another four patients there. Four of the five acutely infected patients had diabetes and received assisted blood glucose sampling by the nursing home staff. The two blood lancet models used in the facility (one each in two sections) were used to obtain blood from multiple patients. The device platforms were not disposable. The lancets were washed only when blood was visible on the device and they were not disinfected. Nurses did not routinely wash their hands or wear gloves when obtaining blood. Two of the five patients with acute nosocomial HBV died of their infections.

In 2008, Gotz et al. reported the investigation of two cases of acute HBV infection among patients at a nursing home in the Netherlands (Ref. 31). The nursing home stay of these two patients overlapped with that of a patient with known chronic HBV infection. Early in this time period, the nursing home changed the lancet device used for glucose monitoring from a spring-loaded device with a disposable platform (used for multiple patients) to a device with a rotating drum dispensing new lancet blades, which was also used to draw blood from multiple patients, although it was labeled for single patient use only. This device was used for about a month until the staff realized that active rotation of the drum was occasionally forgotten, resulting in the reuse of a lancet blade on more than one patient. The new device was then removed from the facility and the spring-loaded lancet was returned to use. The two patients with acute HBV received blood glucose monitoring as did the source patient with chronic HBV, sometimes on the same day. Two other patients who also received blood glucose monitoring escaped infection. The investigators stated that they believed the rotating lancet drum device was likely the means

of transmission of HBV infection between patients.

In 2011, Duffell et al. reported on the investigations of five reports of HBV transmission in community health care settings in the United Kingdom (Ref. 32). All of the nine initially reported patients with HBV had diabetes and were receiving blood glucose monitoring. Further investigation identified another 12 patients with acute HBV infection. The care settings in which hepatitis transmission occurred were described as a "private residential home" (one patient), "nursing and residential home" (one patient), "private nursing and residential home" (one patient) and "local care home" (two patients). Eleven of the 21 acutely infected patients had symptomatic HBV; 7 of these patients died, 5 due to the HBV infection. All of the care sites in which acute HBV transmission occurred were using blood lancets intended for single patient use only; these devices were either routinely or occasionally used for multiple patients. One facility also used a single glucometer for multiple patients and did not clean or disinfect it between patients. The authors also noted that information reported on patients found to have acute HBV infection between 1990 and 2003 identified only four patients with blood glucose monitoring as a possible risk factor; one of these patients was infected as a result of in-hospital transmission from another patient on the same ward, although details were not provided. Between 2004 and 2006, the 9 patients described previously in this document were reported and investigation led to the discovery of an additional 12 cases of health care-related HBV transmission due to the improper use of blood lancets during patient blood glucose monitoring.

VIII. Special Controls

FDA believes that the special controls identified in the paragraphs that follow--in addition to general controls--are necessary to provide reasonable assurance of safety and

effectiveness for this device when it is for single patient use only. Special controls were discussed at the June 26, 2013, reclassification Panel (Ref. 3). The Panel agreed that the special controls as presented would provide a reasonable assurance of safety and effectiveness for these devices, emphasizing in discussions the need for adequate labeling for these devices. FDA believes that the special controls proposed for single use only blood lancets with an integral sharps injury prevention feature in § 878.4850(a)(2), in addition to the general controls, mitigate the risks to health discussed in section V and are necessary to provide reasonable assurance of safety and effectiveness.

Table 1 depicts how each risk to health would be mitigated by the proposed special controls.

Table 1.--Health Risks and Mitigation Measures for Single Use Only Blood Lancet With an Integral Sharps Injury Prevention Feature

Identified Risk	Mitigation Measure
Bloodborne pathogen transmission	Design characteristics Mechanical performance testing Labeling
Sharp object injuries	Design characteristics Mechanical performance testing Labeling
Local tissue infection	Labeling Sterilization
Adverse tissue reaction (not infection)	Biocompatibility

FDA believes that the special controls proposed for single use only blood lancets without an integral sharps injury prevention feature in proposed in § 878.4850(b)(2), in addition to the general controls, mitigate these risks to health discussed in section V and are necessary to provide reasonable assurance of safety and effectiveness.

Table 2 depicts how each risk to health would be mitigated by the proposed special controls.

Table 2.--Health Risks and Mitigation Measures for Single Use Only Blood Lancet Without an Integral Sharps Injury Prevention Feature

Identified Risk	Mitigation Measure
Bloodborne pathogen transmission	Design characteristics Mechanical performance testing Labeling
Sharp object injuries	Design characteristics Mechanical performance testing Labeling
Local tissue infection	Labeling Sterilization
Adverse tissue reaction (not infection)	Biocompatibility

FDA believes that the special controls proposed for multiple use blood lancets for single patient use only in proposed § 878.4850(c)(2), in addition to the general controls, mitigate these risks to health discussed in section V and are necessary to provide reasonable assurance of safety and effectiveness.

Table 3 depicts how each risk to health would be mitigated by the proposed special controls.

Table 3.--Health Risks and Mitigation Measures for Multiple Use Blood Lancet for Single Patient Use Only

Identified Risk	Mitigation Measure
Bloodborne pathogen transmission	Design characteristics Mechanical performance testing Labeling
Sharp object injuries	Design characteristics Mechanical performance testing Labeling
Local tissue infection	Labeling Sterilization Validated cleaning and disinfection

Adverse tissue reaction (not infection)	Biocompatibility
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IX. The Proposed Order

FDA is issuing this proposed order to reclassify the following three types of blood lancets used to puncture skin to obtain a drop of blood for diagnostic purposes from class I (general controls) exempt from premarket notification into class II (special controls) and subject to premarket review: (1) Single use only blood lancets with an integral sharps injury prevention feature, (2) single use only blood lancets without an integral sharps injury prevention feature, and (3) multiple use blood lancets for single patient use only. FDA is identifying proposed special controls for these types of blood lancets, as identified in section VIII of this document, that are necessary to provide a reasonable assurance of safety and effectiveness. FDA is also proposing to reclassify multiple use blood lancets for multiple patient use from class I (general controls) exempt from premarket notification into class III (premarket approval).

X. Effective Date

FDA proposes that any final order based on this draft order become effective on its date of publication in the Federal Register.

- Blood lancets for single patient use only that have not been offered for sale prior to the effective date of the final order, or have been offered for sale but are required to submit a new 510(k) under 21 CFR 807.81(a)(3): Manufacturers would have to obtain 510(k) clearance before marketing their devices after the effective date of the order. If a manufacturer markets such a device without receiving 510(k) clearance,

then FDA would consider taking action against such a manufacturer under its usual enforcement policies.

- Blood lancets for single patient use only that have been offered for sale prior to the effective date of the final order, and do not already have 510(k) clearance: FDA does not intend to enforce compliance with the 510(k) requirement or special controls until 180 days after the effective date of the final order. After that date, if a manufacturer continues to market such a device but does not have 510(k) clearance or FDA determines that the device is not substantially equivalent or not compliant with special controls, then FDA would consider taking action against such manufacturer under its usual enforcement policies.

For blood lancets for single patient use that have prior 510(k) clearance, FDA would accept a new 510(k) and would issue a new clearance letter, as appropriate, indicating substantial equivalence and special controls compliance. These devices could serve as predicates for new devices. These clearance letters would be made publicly available in FDA's 510(k) database, and compliance with special controls at the time of clearance would be stated in the publically available 510(k) Summary posted in this database. Since many blood lancets for single patient use are non-prescription ("over the counter") devices, FDA believes that our public database is a transparent tool allowing consumers to confirm that their devices have been submitted under a new 510(k) and demonstrated conformance to applicable special controls. Elsewhere in this issue of the Federal Register, FDA is proposing to require the filing of a PMA or notice of completion

of a PDP for multiple use blood lancets for multiple patient use, which will be finalized only if FDA reclassifies these devices into class III.

XI. Analysis of Environmental Impact

We have determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

XII. Paperwork Reduction Act of 1995

This proposed order refers to previously approved information collections found in FDA regulations. The collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910-0120. The collections of information in 21 CFR part 801 have been approved under OMB control number 0910-0485. The collections of information in 21 CFR part 820 have been approved under OMB control number 0910-0073. The collections of information in 21 CFR part 814, subparts B and E, have been approved under OMB control number 0910-0231.

The labeling provisions in proposed § 878.4850(a)(2)(vi), (b)(2)(vi), and (c)(2)(vii) are not subject to review by OMB because they do not constitute a "collection of information" under the PRA. Rather, the following labeling: (1) "For use only on a single patient. Discard the entire device after use."; (2) "For use only on a single patient. Disinfect reusable components according to manufacturer's instructions between each use."; (3) "Used lancet blades must be discarded safely after a single use."; (4) "Warning: Not intended for more than one use. Do not use on more than one patient. Improper use of blood lancets can increase the risk of inadvertent transmission of bloodborne pathogens, particularly in settings where multiple patients are

tested."; and (5) "Warning: Do not use on more than one patient. Improper use of blood lancets can increase the risk of inadvertent transmission of bloodborne pathogens, particularly in settings where multiple patients are tested. The cleaning and disinfection instructions for this device are intended only to reduce the risk of local use site infection; they cannot render this device safe for use for more than one patient." are a "public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public" (5 CFR 1320.3(c)(2)).

XIII. Codification of Orders

Prior to the amendments by FDASIA, section 513(e) of the FD&C Act provided for FDA to issue regulations to reclassify devices. Although section 513(e) as amended requires FDA to issue final orders rather than regulations, FDASIA also provides for FDA to revoke previously issued regulations by order. FDA will continue to codify classifications and reclassifications in the Code of Federal Regulations (CFR). Changes resulting from final orders will appear in the CFR as changes to codified classification determinations or as newly codified orders. Therefore, under section 513(e)(1)(A)(i), as amended by FDASIA, in the proposed order, we are proposing to revoke the requirements in § 878.4800 related to the classification of blood lancets as class I devices and to codify the reclassification of subsets of blood lancets into class II or class III in § 878.4850.

XIV. References

The following references are on display in the Division of Dockets Management (see ADDRESSES) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at <http://www.regulations.gov>.

FDA has verified the Web site addresses, as of the date this document publishes in the Federal Register, but Web sites are subject to change over time.

1. U.S. Food and Drug Administration (FDA), "Use of Fingerstick Devices on More Than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication" (August 26, 2010) and "Update" (November 29, 2010), available at

<http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm234889.htm> and

<http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm>.

2. U.S. Food and Drug Administration, "Guidance for Industry and Food and Drug Administration Staff: Blood Lancet Labeling" (November 29, 2010), available at

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm234577.htm>.

3. FDA's General and Plastic Surgery Devices Panel transcript and other meeting materials for the June 26, 2013, meeting are available on FDA's Web site at <http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/GeneralandPlasticSurgeryDevicesPanel/ucm349426.htm>.

4. Centers for Disease Control and Prevention (CDC). "Nosocomial Transmission of Hepatitis B Virus Associated With a Spring-Loaded Fingerstick Device--California", MMWR Morbidity and Mortality Weekly Report, 1990; 39 (35):610-613. (Available at:

<http://www.cdc.gov/mmwr/preview/mmwrhtml/00001743.htm>)

5. Food and Drug Administration (FDA), "Safety Alert Medical Devices; Hepatitis B Transmission via Spring-Loaded Lancet Devices" (August 28, 1990), available at

<http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PublicHealthNotifications/ucm241809.htm>.

6. Centers for Disease Control and Prevention (CDC), "CDC Clinical Reminder Use of Fingerstick Devices on More Than One Person Poses Risk for Transmitting Bloodborne Pathogens", available at <http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html>.

7. Polish, L., C. Shapiro, F. Bauer, et al., "Nosocomial Transmission of Hepatitis B Virus Associated With the Use of a Spring-Loaded Fingerstick Device", New England Journal of Medicine, 1992; 326 (11):721-725.

8. Douvin, C., D. Simon, H. Zinelabidine, et al., "An Outbreak of Hepatitis B in an Endocrinology Unit Traced to a Capillary Blood Sampling Device", New England Journal of Medicine, 1990; 322:57-58.

9. Shier, N., J. Warren, M. Torabi, et al., "Contamination of a Fingerstick Device", New England Journal of Medicine, 1993; 328:969-970.

10. Schmid, R., "History of Viral Hepatitis: A Tale of Dogmas and Misinterpretations", Journal of Gastroenterology and Hepatology, 2001; 16(7):718-722.

11. Graham, G., "Diabetes Mellitus: A Survey of Changes in Treatment During the Last Fifteen Years", The Lancet, 1938 2:1-7.

12. Droller, H., "An Outbreak of Hepatitis in a Diabetic Clinic", British Medical Journal, 1945; 1(4400):623-625.

13. Stapleton, J., and S. Lemon, "Transmission of Hepatitis B During Blood Glucose Monitoring", Journal of the American Medical Association 1985; 253:3250.

14. Farkas K and G Jermendy. "Transmission of Hepatitis B Infection During Home Blood Glucose Monitoring", Diabetic Medicine, 1997; 14:263.
15. Mendez, L., K.R. Reddy, R.A. Di Prima, et al., "Fulminant Hepatic Failure Due to Acute Hepatitis B and Delta Co-Infection: Probable Bloodborne Pathogen Transmission Associated With a Spring-loaded Fingerstick Device", American Journal of Gastroenterology, 1991; 86:895-897.
16. Centers for Disease Control and Prevention (CDC), "Nosocomial Hepatitis B Virus Infection Associated With Reusable Fingerstick Blood Sampling Devices--Ohio and New York City, 1996", MMWR Morbidity and Mortality Weekly Report, 1997; 46(10):217-221. (Available at: <http://www.cdc.gov/mmwr/preview/mmwrhtml/00046679.htm>.)
17. Quale, J.M., D. Landman, B. Wallace, et al., "Déjà vu: Nosocomial Hepatitis B Transmission and Fingerstick Monitoring", The American Journal of Medicine, 1998; 105:296-301.
18. Thompson, N.D., J. Perz, A. Moorman, et al., "Nonhospital Health Care-Associated Hepatitis B and C Virus Transmission: United States, 1998-2008", Annals of Internal Medicine, 2009; 150:33-39.
19. Khan, A.J., S.M. Cotter, B. Schulz, et al., "Nosocomial Transmission of Hepatitis B Virus Infection Among Residents With Diabetes in a Skilled Nursing Facility", Infection Control and Hospital Epidemiology, 2002; 23:313-318.
20. Centers for Disease Control and Prevention (CDC), "Transmission of Hepatitis B Virus Among Persons Undergoing Blood Glucose Monitoring in Long-Term-Care Facilities--Mississippi, North Carolina, and Los Angeles County, California, 2003-2004", MMWR

Morbidity and Mortality Weekly Report, 2005; 54(09):220-223. (Available at:

<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5409a2.htm>.)

21. Thompson, N.D. and J.F. Perz, "Eliminating the Blood: Ongoing Outbreaks of Hepatitis B Virus Infection and the Need for Innovative Glucose Monitoring Techniques", Journal of Diabetes Science and Technology, 2009; 3(2):283-288.

22. Thompson, N.D., V. Barry, K. Alelis, et al., "Evaluation of the Potential for Bloodborne Pathogen Transmission Associated With Diabetes Care Practices in Nursing Homes and Assisted Living Facilities, Pinellas County", Journal of the American Geriatrics Society, 2010; 58:914-918.

23. Patel, A.S., M.B. White-Comstock, D. Woolard, et al., "Infection Control Practices in Assisted Living Facilities: A Response to Hepatitis B Virus Infection Outbreaks", Infection Control and Hospital Epidemiology, 2009; 30:209-214.

24. Centers for Disease Control and Prevention (CDC), "Multiple Outbreaks of Hepatitis B Virus Infection Related to Assisted Monitoring of Blood Glucose Among Residents of Assisted Living Facilities--Virginia, 2009-2011", MMWR Morbidity and Mortality Weekly Report, 2012; 61(19):339-343. (Available at:

http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6119a3.htm?s_cid=mm6119a3_w.)

25. Centers for Disease Control and Prevention (CDC), "Notes From the Field: Deaths From Acute Hepatitis B Virus Infection Associated With Assisted Blood Glucose Monitoring in an Assisted-Living Facility--North Carolina, August-October, 2010", MMWR Morbidity and Mortality Weekly Report, 2011; 60(6):182. (Available at:

http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6006a5.htm?s_cid=mm6006a5_w.)

26. Schaefer, M.K., M. Jhung, M. Dahl, et al., "Infection Control Assessment of Ambulatory Surgical Centers", Journal of the American Medical Association, 2010; 303 (22):2273-2279.

27. Thompson, N.D. and M.K. Schaeffer, " 'Never Events': Hepatitis B Outbreaks and Patient Notifications Resulting From Unsafe Practices During Assisted Monitoring of Blood Glucose, 2009-2010", Journal of Diabetes Science and Technology, 2011; 5(6):1396-1402.

28. Centers for Disease Control and Prevention (CDC), "Notes From the Field: Transmission of HBV Among Assisted-Living-Facility Residents--Virginia, 2012", MMWR Morbidity and Mortality Weekly Report, 2013; 62(19):389. (Available at: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6219a4.htm?s_cid=mm6219a4_w.)

29. Desenclos, J.C., M. Bourdiol-Razes, B. Rolin, et al., "Hepatitis C in a Ward for Cystic Fibrosis and Diabetic Patients: Possible Transmission by Spring-Loaded Finger-Stick Devices for Self-Monitoring of Capillary Blood Glucose", Infection Control and Hospital Epidemiology, 2001; 22(11):701-707.

30. De Schrijver, K., I. Maes, P. Van Damme, et al., "An Outbreak of Nosocomial Hepatitis B Virus Infection in a Nursing Home for the Elderly in Antwerp (Belgium)", Acta Clinica Belgica, 2005; 60(2):63-69.

31. Gotz, H.M., M. Schutten, G.J. Borsboom, et al., "A Cluster of Hepatitis B Infections Associated With Incorrect Use of a Capillary Blood Sampling Device in a Nursing Home in the Netherlands, 2007", Euro Surveillance, 2008; 13(7-9):1-5.

32. Duffell, E.F., L.M. Milne, C. Seng, et al., "Five Hepatitis B Outbreaks in Care Homes in the UK Associated With Deficiencies in Infection Control Practice in Blood Glucose Monitoring", Epidemiology and Infection, 2011; 139:327-335.

33. Williams, I.T., J.F. Perz, and B.P. Bell, "Viral Hepatitis Transmission in Ambulatory Health Care Settings", Clinical Infectious Diseases, 2004; 38(11):1592-1598.

34. Centers for Disease Control and Prevention (CDC), "Increasing Prevalence of Diagnosed Diabetes--United States and Puerto Rico, 1995-2010", MMWR Morbidity and Mortality Weekly Report, 2012; 61(45):918-921. (Available at: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6145a4.htm?s_cid=mm6145a4_w.)

35. Centers for Disease Control and Prevention (CDC), "Incidence of Diagnosed Diabetes per 1,000 Population Aged 18-79 Years, by Age, 1980-2014", Atlanta, GA: U.S. Department of Health and Human Services, CDC, National Diabetes Surveillance System. Available at www.cdc.gov/diabetes/statistics/incidence/fig3.htm. Accessed October 19, 2014.

36. Clarke, S.F. and J.R. Foster, "A History of Blood Glucose Meters and Their Role in Self-Monitoring of Diabetes Mellitus", British Journal of Biomedical Science, 2012; 69(2):83-93.

37. Yoo, E.-H. and S.-Y. Lee, "Glucose Biosensors: An Overview of Use in Clinical Practice", Sensors, 2010; 10(5):4558-4576.

38. Rajendran, R. and G. Rayman, "Point-of-Care Blood Glucose Testing for Diabetes Care in Hospitalized Patients: An Evidence-Based Review", Journal of Diabetes Science and Technology, 2014; 8(6):1081-1090.

39. Centers for Disease Control and Prevention (CDC), "Use of Hepatitis B Vaccination for Adults With Diabetes Mellitus: Recommendations of the Advisory Committee on Immunization Practices (ACIP)", MMWR Morbidity and Mortality Weekly Report, 2011; 60(50):1709-1711. (Available at: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6050a4.htm?s_cid=mm6050a4_w.)

40. Centers for Medical Services (CMS), "Survey and Certification Memorandum" (August 27, 2010), available at http://www.cms.gov/surveycertificationgeninfo/downloads/SCLetter10_28.pdf.

List of Subjects in 21 CFR Part 878

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 878 be amended as follows:

PART 878--GENERAL AND PLASTIC SURGERY DEVICES

1. The authority citation for 21 CFR part 878 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

2. Amend § 878.4800 by revising paragraph (a) to read as follows:

§ 878.4800 Manual surgical instrument for general use.

(a) Identification. A manual surgical instrument for general use is a nonpowered, hand-held, or hand-manipulated device, either reusable or disposable, intended to be used in various general surgical procedures. The device includes the applicator, clip applier, biopsy brush, manual dermabrasion brush, scrub brush, cannula, ligature carrier, chisel, clamp, contractor,

curette, cutter, dissector, elevator, skin graft expander, file, forceps, gouge, instrument guide, needle guide, hammer, hemostat, amputation hook, ligature passing and knot-tying instrument, knife, mallet, disposable or reusable aspiration and injection needle, disposable or reusable suturing needle, osteotome, pliers, rasp, retainer, retractor, saw, scalpel blade, scalpel handle, one-piece scalpel, snare, spatula, stapler, disposable or reusable stripper, stylet, suturing apparatus for the stomach and intestine, measuring tape, and calipers. A surgical instrument that has specialized uses in a specific medical specialty is classified in separate regulations in parts 868 through 892 of this subchapter.

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3. Add § 878.4850 to subpart E to read as follows:

§ 878.4850 Blood lancets.

(a) Single use only blood lancet with an integral sharps injury prevention feature—(1) Identification. A disposable blood lancet intended for a single use that is comprised of a single use blade attached to a solid, non-reusable base (including an integral sharps injury prevention feature) that is used to puncture the skin to obtain a drop of blood for diagnostic purposes. The integral sharps injury prevention feature allows the device to be used once and then renders it inoperable and incapable of further use.

(2) Classification. Class II (special controls). The special controls are:

(i) The design characteristics of the device must ensure that the structure and material composition are consistent with the intended use and must include a sharps injury prevention feature;

(ii) Mechanical performance testing must demonstrate that the device will withstand forces encountered during use and that the integral sharps injury prevention feature will irreversibly disable the device after one use;

(iii) The device must be demonstrated to be biocompatible;

(iv) Sterility testing must demonstrate the sterility of the device;

(v) Labeling must include:

(A) Detailed descriptions, with illustrations, of the proper use of the device and its sharps injury prevention feature.

(B) Handwashing instructions for the user before and after use of the device.

(C) Instructions on cleaning and disinfection of the skin to be pierced.

(D) Instructions for the safe disposal of the device.

(E) Labeling must be appropriate for the intended use environment.

(1) For those devices intended for health care settings, labeling must address the health care facility use of these devices, including how these lancets are to be used with personal protective equipment, such as gloves.

(2) For those devices intended for use in the home, labeling must be written so that it is understandable to lay users.

(vi) Labeling must also include the following statements, prominently placed:

(A) "For use only on a single patient. Discard the entire device after use."

(B) "Warning: Not intended for more than one use. Do not use on more than one patient. Improper use of blood lancets can increase the risk of inadvertent transmission of bloodborne pathogens, particularly in settings where multiple patients are tested."

(b) Single use only blood lancet without an integral sharps injury prevention feature—(1)

Identification. A disposable blood lancet intended for a single use that is comprised of a single use blade attached to a solid, non-reusable base that is used to puncture the skin to obtain a drop of blood for diagnostic purposes.

(2) Classification. Class II (special controls). The special controls are:

- (i) The design characteristics of the device must ensure that the structure and material composition are consistent with the intended use and address the risk of sharp object injuries and bloodborne pathogen transmissions;
- (ii) Mechanical performance testing must demonstrate that the device will withstand forces encountered during use;
- (iii) The device must be demonstrated to be biocompatible;
- (iv) Sterility testing must demonstrate the sterility of the device;
- (v) Labeling must include:
 - (A) Detailed descriptions, with illustrations, of the proper use of the device.
 - (B) Handwashing instructions for the user before and after use of the device.
 - (C) Instructions on cleaning and disinfection of the skin to be pierced.
 - (D) Instructions for the safe disposal of the device.
 - (E) Labeling must be appropriate for the intended use environment.
- (1) For those devices intended for health care settings, labeling must address the health care facility use of these devices, including how these lancets are to be used with personal protective equipment, such as gloves.

(2) For those devices intended for use in the home, labeling must be written so that it is understandable to lay users.

(vi) Labeling must also include the following statements, prominently placed:

(A) "For use only on a single patient. Discard the entire device after use."

(B) "Warning: Not intended for more than one use. Do not use on more than one patient. Improper use of blood lancets can increase the risk of inadvertent transmission of bloodborne pathogens, particularly in settings where multiple patients are tested."

(c) Multiple use blood lancet for single patient use only—(1) Identification. A multiple use capable blood lancet intended for use on a single patient that is comprised of a single use blade attached to a solid, reusable base that is used to puncture the skin to obtain a drop of blood for diagnostic purposes.

(2) Classification. Class II (special controls). The special controls are:

(i) The design characteristics of the device must ensure that:

(A) The lancet blade can be changed with every use, either manually or by triggering a blade storage unit to discard the used blade and reload an unused blade into the reusable base; and

(B) The structure and material composition are consistent with the intended use and address the risk of sharp object injuries and bloodborne pathogen transmissions; and allow for validated cleaning and disinfection;

(ii) Mechanical performance testing must demonstrate that the device will withstand forces encountered during use;

(iii) The device must be demonstrated to be biocompatible;

- (iv) Sterility testing must demonstrate the sterility of the device;
- (v) Validation testing must demonstrate that the cleaning and disinfection instructions are adequate to ensure that the reusable lancet base can be cleaned and low level disinfected.
- (vi) Labeling must include:
 - (A) Detailed descriptions, with illustrations, of the proper use of the device.
 - (B) The Environmental Protection Agency (EPA) registered disinfectant's contact time for disinfectant use.
 - (C) Handwashing instructions for the user before and after use of the device.
 - (D) Instructions on cleaning and disinfection of the skin to be pierced.
 - (E) Instructions on the cleaning and disinfection of the device.
 - (F) Instructions for the safe disposal of the device.
 - (G) Instructions for use must address the safe storage of the reusable blood lancet base between uses to minimize contamination or damage and the safe storage and disposal of the refill lancet blades.
 - (H) Labeling must be appropriate for the intended use environment.
- (1) For those devices intended for health care settings, labeling must address the health care facility use of these devices, including how these lancets are to be used with personal protective equipment, such as gloves.
- (2) For those devices intended for use in the home, labeling must be written so that it is understandable to lay users.
- (vii) Labeling must also include the following statements, prominently placed:

(A) "For use only on a single patient. Disinfect reusable components according to manufacturer's instructions between each use."

(B) "Used lancet blades must be safely discarded after a single use."

(C) "Warning: Do not use on more than one patient. Improper use of blood lancets can increase the risk of inadvertent transmission of bloodborne pathogens, particularly in settings where multiple patients are tested. The cleaning and disinfection instructions for this device are intended only to reduce the risk of local use site infection; they cannot render this device safe for use for more than one patient."

(d) Multiple use blood lancet for multiple patient use—(1) Identification. A multiple use capable blood lancet intended for use on multiple patients that is comprised of a single use blade attached to a solid, reusable base that is used to puncture the skin to obtain a drop of blood for diagnostic purposes.

(2) Classification. Class III (premarket approval).

Dated: February 25, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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